

REMARKS

Claim 36 is currently amended. Claims 1-35 are cancelled without prejudice. Claims 40-62 are newly added. Claims 36-62 are currently pending. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

I. DETAILED ACTION

The Examiner has noted that “This is the *initial* Office action based on the 10/595,536 application filed August 1, 2006, as amended.’ (The ‘536 application). The Examiner indicated that the filing date of the ‘536 application is ‘August 1, 2006.’ Applicants respectfully draw the Examiner’s attention to the fact that this application is an application under §371 which has a §371(c) date of February 8, 2007, but which is based on a PCT application filed July 29, 2005, which in turn properly claims priority to a provisional application filed July 29, 2004. Additionally, the Examiner indicated that claims 29-39 are pending; however, claim 34 was cancelled in the Preliminary Amendment filed. Therefore, Applicants respectfully draw the Examiner’s attention to the fact that only claims 29-33 and 35-39 were pending at the time this Office Action was prepared.

II. INFORMATION DISCLOSURE STATEMENT

Applicants acknowledge, with appreciation, the Examiner’s indication that the references submitted in the Information Disclosure Statement filed February 8, 2007 and April 26, 2008 have been considered. Applicants look forward to receiving confirmation that the references submitted on June 5, 2008 have also been considered.

III. OBJECTIONS TO THE CLAIMS

The Examiner has objected to the claims for having the following informalities: “claims 29-35 are dependent from claim 36, however, are numbered before claim 36 and should be numbered after claim 26.” *See*, Office Action, p. 2. Applicants have assumed the Examiner meant claim “36” instead of claim “26” and are responding based on that assumption.

Applicants’ claims 29-35 are properly dependent on claim 36. The dependency of these claims changed as a result of amendments made to the claims in the Preliminary Amendment filed by Applicants. Moreover, these claims would be renumbered upon allowance so that claims 29-33,

and 35 would then be numbered after claim 36. However, notwithstanding these observations, Applicants have cancelled claims 29-33 and 35 and re-presented them as new claims 57-62, in order to advance prosecution. Accordingly, Applicants request withdrawal of this objection.

The Examiner has also objected to claims 32 (re-presented as claim 60) and 33 (re-presented as claim 61) asserting that “claims 32 and 33 state ‘the method according to claim 36’ when it appears they should state “the kit according to claim 36.” Claims 32 and 33 have been cancelled and re-presented as claims 60 and 61 with a corrected preamble. Accordingly, Applicants have traversed the objection and respectfully request its withdrawal.

IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

In order for Applicants’ claims to lack novelty under 35 U.S.C. § 102(b) (*i.e.*, be anticipated), each and every element of the claimed invention must be disclosed in a single prior art reference. A prior art reference anticipates a claim *only if* the reference discloses, either expressly or inherently, every limitation of the claim.

The Patent Examiner bears the burden of demonstrating that Applicants’ invention is anticipated by the reference relied on in the Examiner’s reasons for rejection.

For the following reasons, Applicants believe the Examiner has not met this burden.

A. Claims 29, 32, and 35-39 have been rejected under 35 U.S.C. § 102(b) over Reiley et al.

The Examiner has rejected claims 29 (re-presented as claim 57), 32 (represented as claim 60), and 35-39 (35, represented as claim 62) under 35 U.S.C. § 102(b) as being anticipated by Reiley *et al.* (U.S. Patent No. 6,575,919). Claims 29 (now 57), 32 (now 60), 35 (now 62), and 37-39 depend from claim 36. Regarding claim 36, the Examiner asserts that:

Reiley discloses a kit for performing a procedure on a spine, the spine including an epidural space containing a thecal sac, the kit comprising: an insertion member for accessing the epidural space (second instrument [40]); an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space (therapeutic element [132]; col. 10, lines 7-12); and a tool including means for engaging the ligamentum flavum (penetrating surface [35]) and means for

resecting a section of the ligamentum flavum (drill bit instrument [70] including cutting edges [76]). *See* Office Action, pp.3-4.

Reiley *et al.* discloses a device comprising

a tool comprising a first functional instrument having a first handle and a second functional instrument having a second handle. The first functional instrument engages the second functional instrument, forming a composite instrument. The first handle mates with the second handle, forming a composite handle for the composite instrument. The composite handle includes a latching mechanism to resist disengagement of the first and second functional instruments. (Col. 1, lines 54-60).

Additionally, Reiley *et al.* also discloses that “the element 132 can comprise a biopsy instrument, to obtain samples of cancellous bone or to harvest bone marrow...Still alternatively (as shown in FIG. 13), the distal element 132 can comprise an expandable body to compact cancellous bone 102 and form a cavity 134 in the vertebral body 96, in the manner disclosed in U.S. Pat. Nos. 4,969,888, 5,108,404, and 5,827,289, which are incorporated herein by reference.”(Col. 10, lines 3-10).

Reiley *et al.* does not disclose a kit for performing a procedure on a spine, the spine including an epidural space containing a thecal sac, the kit comprising: an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle; and a tool including means for engaging the ligamentum flavum and means for resecting a section of the ligamentum flavum, wherein the insertion member handle and the expandable device handle do not couple to form a composite handle (*emphasis added*).

For the foregoing reasons, Applicants' claim 36 is not anticipated by Reiley *et al.* under 35 U.S.C. § 102(b). Therefore, Applicants request that the Examiner withdraw his rejection of claim 36. Furthermore, claims 29, 32, 35, and 37-39 depend directly or indirectly from claim 36 and include the limitations thereof. For the reasons provided with respect to claim 36, claims 29, 32, 35, and 37-39 are not anticipated by Reiley et al under 35 U.S.C. § 102(b). Therefore,

Applicants also request that the rejection of claims 29, 32, 35, and 37-39 under 35 U.S.C. § 102(b) be withdrawn as well.

V. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)

During patent examination the PTO bears the initial burden of supporting a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence in prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led from the relevant teachings of the applied references to arrive at the claimed invention. This can be shown by showing some teaching, suggestion, incentive or inference to combine the references or showing that there is a design need or market pressure to solve a problem and there are a finite number of identified or predictable solutions a person of ordinary skill in the art has good reason to pursue and that the known objects are within his or her technical grasp. Mere identification in the prior art of each element is insufficient to defeat patentability of the combined subject matter. Further, Applicants' explanation of how the invention works does not render obvious that which is otherwise unobvious. Finally, there must be a reasonable expectation of success and the references must teach or suggest all of the claim limitations.

A *prima facie* case of obviousness can be rebutted if the Applicants can show that the art teaches away from the claimed invention.

Applicants believe the Examiner has not met his burden under § 103(a) for the following reasons:

A. Claim 30 has been rejected under 35 U.S.C. § 103(a) over Reiley et al in view of Bennick, Jr.

The Examiner has rejected Claim 30 (represented as claim 58) under 35 U.S.C. § 103(a) as being unpatentable over Reiley *et al.* (U.S. Patent No. 6,575,919) in view of Bennick, Jr. (U.S. Patent No. 4,283,129). The Examiner asserts that

Regarding claim 30, Reiley discloses the kit according to claim 29, including: a contrast medium as applied to claim 29 above. Reiley does not appear to disclose the kit according to claim 29, wherein: the contrast medium comprises a radio-opaque non-ionic myelographic contrast medium. However, Bennick, a reference in analogous art discloses the kit according to claim 29, where: the

contrast medium comprises a radio-opaque non-ionic myelographic contrast medium (“inject radio opaque dyes” col. 8, lines 16-17). At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Reiley and Bennick before him or her to modify the contrast medium of Reiley to include radio-opaque non-ionic myelographic properties of Bennick. The motivation for doing so would have been “inject radio opaque dyes into a patient and to observe the dyes through radiological methods for diagnostic purposes” (Bennick: col. 8, lines 16-18). *See, Office Action, pp. 5-6.*

Reiley *et al.* does not disclose an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle. Therefore, since neither Reiley *et al.* nor Bennick have anything to do with an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle, the rejection should be withdrawn. Neither reference provides any teaching, suggestion or description of an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle as required by Applicants' claim 30.

Moreover, Applicants respectfully suggest that the proposed combination of Reiley *et al.* with Bennick is improper. One of ordinary skill considering the composite handle tool of Reiley *et al.* would have no motivation whatsoever to consider, combine or modify that device based on Bennick's camera for recording the output of an instrument. Even if some motivation to combine

these references could be identified, such a combination would fail to render Applicants' claim 30 obvious because any such combination would still lack any suggestion of "an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle." For at least these reasons, no combination of these references can render obvious Applicants' claim 30. Claim 30 is therefore allowable under 35 U.S.C. § 103(a). As such, the rejection of claim 30 under 35 U.S.C. § 103(a) should be withdrawn.

B. Claim 31 has been rejected under 35 U.S.C. § 103(a) over Reiley et al in view of Edwards et al.

The Examiner has rejected Claim 31 (re-presented as claim 59) under 35 U.S.C. § 103(a) as being unpatentable over Reiley *et al.* (U.S. Patent No. 6,575,919) in view of Edwards *et al.* (U.S. Patent No. 5,985,320). The Examiner asserts that

Regarding claim 31, Reiley disclose the kit according to claim 36, wherein: said expandable device comprises a volume that is injectable (col. 10, lines 13-36). Reiley does not appear to disclose the kit according to claim 36, wherein: said expandable device comprises a volume that is injectable at ambient temperatures and more viscous at body temperature. However, Edwards, a reference in analogous art discloses the kit according to claim 36, wherein: said expandable device comprises a volume that is injectable at ambient temperatures and more viscous at body temperature (col. 7, lines 50-57). At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Reiley and Edwards before him or her to modify the injectable volume of Reiley to include viscous formulations of Edwards. The motivation for doing so would have been to "provide compositions and methods for enhancing intracellular delivery of bioactive and/or diagnostic agents. It is a further object of the present invention to provide less invasive methods for delivering high molecular weight and labile drugs, such as proteins and nucleic acids, molecules, and diagnostic agents." (Edwards: col. 2, lines 6-13). *See, Office Action, pp. 5-6.*

Reiley *et al.* does not disclose an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle. Therefore, since neither Reiley *et al.* nor Edwards *et al.* have anything to do with an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle, the rejection should be withdrawn. Neither reference provides any teaching, suggestion or description of an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle, as required by Applicants' claim 31.

Applicants respectfully suggest that the proposed combination of Reiley *et al.* with Edwards *et al.* is improper. One of ordinary skill considering the composite handle tool of Reiley *et al.* would have no motivation whatsoever to consider, combine or modify that device based on Edwards' compositions and methods for delivering agents across cell membranes. Moreover, even if some motivation to combine these references could be identified, such a combination would fail to render Applicants' claim 31 obvious because any such combination would still lack any suggestion of "an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle." For at least these reasons, no combination of these references can render obvious Applicants' claim 31. Claim

31 is therefore allowable under 35 U.S.C. § 103. As such, the rejection of claim 31 under 35 U.S.C. § 103 should be withdrawn.

C. Claim 33 has been rejected under 35 U.S.C. § 103(a) over Reiley et al in view of Sharps et al.

The Examiner has rejected Claim 33 (represented as claim 61) under 35 U.S.C. § 103(a) as being unpatentable over Reiley *et al.* (U.S. Patent No. 6,575,919) in view of Sharps *et al.* (U.S. Patent No. 6,602,248). The Examiner asserts that

Regarding claim 33, Reiley discloses the method according to claim 35 (see claim objection), including: a contrast medium as applied to claim 29 above. Reiley does not appear to disclose the kit according to claim 29, wherein: the contrast medium includes a steroid.

However, Sharp, a reference in analogous art discloses disclose the kit according to claim 29, wherein: the contrast medium includes a steroid (“epidural steroid injection” col. 55, line 13). At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Reiley and Sharps before him or her to modify the contrast medium of Reiley to include the steroid properties of Sharps. The motivation for doing so would have been “diminished perineural inflammation of an affected nerve root, leading to alleviation of dicogenic pain” to provide “significant improved patient care” (Sharps: col. 55, lines 13-25). *See, Office Action, p. 8.*

Reiley *et al.* does not disclose an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle. Therefore, since neither Reiley *et al.* nor Sharps *et al.* have anything to do with an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle, the rejection should be withdrawn. Neither reference provides any teaching, suggestion or description of an insertion

member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle as required by Applicants' claim 33.

Applicants suggest that the proposed combination of Reiley *et al.* with Sharps *et al.* is improper. One of ordinary skill considering the composite handle tool of Reiley *et al.* would have no motivation whatsoever to consider, combine or modify that device based on Sharps' device for repairing damaged intervertebral discs. Moreover, even if some motivation to combine these references could be identified, such a combination would fail to render Applicants' claim 33 obvious because any such combination would still lack any suggestion of "an insertion member for accessing the epidural space, the insertion member comprising a handle; an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space, the expandable device comprising a handle...wherein the insertion member handle and the expandable handle do not couple to form a composite handle." For at least these reasons, no combination of these references can render obvious Applicants' claim 33. Claim 33 is therefore allowable under 35 U.S.C. § 103(a). As such, the rejection of claim 33 under 35 U.S.C. § 103(a) should be withdrawn.

VI. NEWLY PRESENTED CLAIMS

Applicants have presented new claims 40-62. Support for the newly presented claims can be found throughout pages 9 and 10 and throughout the specification in general. Therefore, Applicants believe that the newly presented claims present no new matter and are also allowable.

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Reply to Office Action of May 12, 2008

CONCLUSION

For the foregoing reasons, Applicants request that the Examiner allow claims 36-62 and advance the application to issuance.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 36930-704.831).

Respectfully submitted,

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